product of the prior art, the claim is unpatentable even though the prior product was made by a different process. The Applicant respectfully traverses.

Claim 11 is not anticipated by Anderson et al. not only because Anderson et al. does not teach or suggest a heat shrink step, but because the final products are physically distinct. Evidence of this can be found in the Applicant's specification, for example, in examples 2, 4 and 5 and figures 3-4. These examples show the effect the shrinking step has on the physical properties of the balloons, i.e. their charted physical reaction to pressurization as compared to balloons that were not subjected to a heat shrinking step. In the second heat step of Anderson et al., instead of reducing the temperature relative to the first heat step, as required by the present invention, it requires that the temperature in the second step be increased. As such, it cannot be presumed, in view of the comparisons shown in the Applicant's specification, that different processes of production applying different parameters would produce balloons that are physically the same. This contradicts the Examiner's assumption in the product-by-process analysis in the final official action.

Anderson et al. does not disclose or teach each and every element as set forth in claim 11 of the present application. In claim 11, an annealing process which includes heating the balloon material twice at different elevated temperatures and different pressures, wherein the second temperature and pressure are less than the first temperature and pressure. This process results in a shrinking of the balloon's diameter. The balloons prepared utilizing the shrinking step have extended, very high compliance profiles, in addition to high wall strength. The shrinking step causes the compliance curve to start from a lower point so that overall the balloon is much more compliant. The presently claimed invention provides unique combinations of balloon diameter, high burst strength and high compliance characteristics and also provides excellent rewrap characteristics, in comparison to high strength balloons formed by other processes. With the shrinking step, the force required to withdraw the balloon catheter from the body is low, especially for catheters designed to pass through endoscopes. These are distinct physical characteristics which are displayed by a balloon made by a process utilizing a heat shrinking step, which is not suggested in, and in fact discouraged by, Anderson et al.

Anderson et al. specifically teaches away from the heat shrinking step of the present invention and at the same time claims that the improved properties of its balloon result from the method or process it teaches to form the balloons (see abstract and col 6, lines 13-23 and lines 29-32). It is asserted in Anderson et al. that "[t]he balloons formed using the process...will have an overall advantageous combination of **physical** properties...superior to those exhibited by the "compliant" balloons currently available." The heat set step taught by Anderson et al. clearly is used to contribute to these improved physical properties. The heat step is used "to provide the expanded parison and resulting balloon with thermal and dimensional stability" (col. 7, lines 5-7). "The stability results from the fact that the balloon is heated above the temperature used in the balloon forming process so that the orientation resulting from the processing condition is "locked" into position." (Col. 8, lines 55-60) It is further stated that during the heat step, the parison "is held at a temperature above the temperature at which the balloon was axially stretched and radially expanded, but below the melting temperature of the polymeric material from which the parison was formed." Once again, "[t]his higher temperature induces crystallization and "freezes" or "locks" the orientation of the polymer chains" (col 9, lines 57-62). The final physical properties of the balloons are dependent upon this heat set step. Lowering the heat set temperature results in balloons exhibiting physical properties which would more likely be adversely affected during a sterilization process (see col. 10, lines 24-27). Balloons created using the heat set step "displayed an improved overall combination of distensibility, elastic stress response and strength when compared to "compliant" balloons of the art" (col 11, lines 48-51). These are all "physical" characteristics which are affected by the heat set step. Example 4 illustrates the importance of the heat set step. From all of the teachings, one can logically conclude that a process not using a heat set step would result in a physically and structurally different balloon. Such is the case with a balloon made using the steps of claim 11. Not only does claim 11 not include a heat set step, which crystallizes the balloon, making is less compliant and more rigid, claim 11 directs one to go in the opposite direction by requiring in the second step that the balloon be heated to a temperature **less** than the first elevated temperature, thus "heat shrinking" the balloon. This results in a more compliant balloon and, as mentioned

above, a physically different balloon.

In the process of Anderson et al., after formation of the balloon, the balloon is heated under pressure of 100-500 psi to a temperature **above** the blowing temperature specifically for the purpose of stabilizing/crystallizing the balloon **against shrinkage upon cooling**. The present invention is directed to exploitation of shrinkage behavior in order to increase and extend the compliance of the resulting balloon. The entire Anderson et al. patent teaches the heat step at an increased second temperature, relative to the initial blowing temperature. Examples of this specific teaching are shown in the patent at Column 9, lines 53-61, Column 10, lines 10-15 and in Example 1. This heat step throughout Anderson et al. teaches in the opposite direction as that of the present application and claim 11 which requires a lower second temperature and pressure relative to the initial blowing temperature and pressure resulting in a structurally different balloon. The second step of both the presently claimed invention and the Anderson et al. invention is an important step in both inventions in affecting the physical characteristics of the final product. As such, logic dictates that since the second steps of the two teaches are distinctly different, the resulting balloons are distinctly different and therefore claim 11 is clearly distinct and not anticipated by Anderson et al. As agreed, claim 11 requires a step clearly not taught by Anderson et al. and in addition, as discussed above, the final products are structurally different and consequently, reconsideration is respectfully requested.

Rejections under 35 U.S.C. §103(a)

(4)

Claims 12-17, 35-42, 44 and 45 were rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose all the different variations of inflation pressure and diameter as claimed. However, it is asserted that, it would be obvious to modify Anderson et al. by providing all the different variations of inflation pressure and diameter to the balloon as an obvious design choice by varying and controlling the specifications in the process of making the balloon. The Applicant respectfully traverses.

With regard to claims 12-17, as discussed above in the response to the §102 rejection, Anderson et al. does not disclose the invention substantially as claimed (claim 11), primarily because of the disparagement between the shrinking step of claim 11 and the heating step of Anderson et al. As a result and due to their dependency, claims 12-17 are similarly not made obvious because Anderson et al. does not disclose the invention substantially as claimed, which is an important basis to the rejection in question, and as such the rejection fails. Still further, as discussed above, one skilled in the art would be led in the wrong direction by Anderson et al. in his experimentation of utilizing the two step process to produce a specific compliance. Anderson et al. specifically teaches balloons which are less compliant than the present invention and unlikely to fall within the scope of claims 12-17.

As to claims 35-42, 44 and 45, which are not dependent on claim 11, are still further not obvious for the basic and resulting difference between the shrinking step of the present invention and the heating step of Anderson et al. Claims 35-42, 44 and 45 define a balloon having an overall compliance and burst pressure which may be achieved using the presently claimed method of making. As pointed out above, Anderson et al. teaches a distinctly different method which results in a more rigid, less compliant balloon. Therefor, it would not be obvious from the teachings of Anderson et al. to create a balloon which is compliant and strong enough to fall within the scope of claims 35-42, 44 and 45. The balloons prepared utilizing the shrinking step have extended and very high compliance profiles, in addition to high wall strength. The heat step of Anderson et al. crystallizes or freezes the balloon, making the balloon material more rigid and less compliant. As mentioned above, the shrinking step of the present application causes the compliance curve to start from a lower point so that overall the balloon is much more compliant. A balloon made using the method and materials of the present invention exhibit certain characteristics due to those materials and shrinking method. These characteristics are exemplified in claims 35-42, 44 and 45, by claiming how the balloon performs under certain pressure. These characteristics at each point in time, or pressure, define the extended, high compliance curve, which is the result of the materials used and the shrinking method employed. As discussed above, Anderson et al. teaches a distinctly different method of making balloons

than that of the presently claimed invention and discloses distinct reasons for the differences in the methods. The present invention seeks **to shrink** the balloon, for the above-mentioned reasons, and Anderson et al. teaches a heat step to stabilize/crystallize the balloon to **guard against shrinkage upon cooling**. The resulting characteristics defined in the claims under rejection are a result of the method of the presently claimed invention and are not taught by Anderson et al. They are not disclosed because the resulting balloons made by the method of Anderson et al. have distinct and different characteristics due to the above discussed differences in the methods of making balloons, most notably the differences between the shrinking step of the present invention and the heat step of Anderson et al. Therefore, it is not suggested or obvious in light of Anderson et al. that the balloon characteristics at certain pressures claimed in the rejected claims, which define the improved compliance curve of balloons made by the method of the presently claimed invention, would be obtained from Anderson et al. even with simple variations of the specifications in the process of making the balloon without the distinctive shrinking methodology of the present invention.

The claimed method is clearly distinct from the methods of Anderson et al., resulting in balloons having differing characteristics, such that the claimed resulting characteristics of the balloons as defined in claims 35-42 and 44-45 would not be obvious over Anderson et al. by merely varying and controlling the specifications in the process of making the balloon, absent the benefit of Applicant's disclosure. In fact, Anderson et al. teaches away from shrinkage to increase compliancy causing any experimentation to result in a balloon which would not fulfil the requirements of claims 35-42 and 44-45. Specifically, Anderson et al. directs one to use a heat set step and not a heat shrink step, which, as discussed above, is a distinctly different process resulting in a distinctly different balloon. Therefore, Applicant respectfully submits that the rejection has been overcome and requests that the rejection be withdrawn.

Claim 43 was rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of U.S. Patent No. 5,344,400 to Kaneko et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose the balloon formed from at least two concentric layers of different thermoplastic polymers. However, it is asserted

that Kaneko et al. teaches a balloon having the missing limitation, and that it would have been obvious to combine the two reference making claim 43 obvious.

In response, Applicant asserts that Anderson et al. does not disclose the invention substantially as claimed, and therefore the rejection fails. Claim 43 depends upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40, Anderson et al. does not disclose the invention substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejection be withdrawn.

The Examiner also rejects claims 46 and 47 under 35 U.S.C. §103(a) as being unpatentable over Anderson et al. in view of U.S. Patent No. 5,167,239 to Cohen et al. It is asserted that Anderson et al. discloses the invention substantially as claimed, but does not disclose a method of treating a gastrointestinal lesion having the steps as claimed by Applicant. However, it is asserted that Cohen et al. teaches a device having the missing limitation, and that it would have been obvious to combine the two reference making claims 46 and 47 obvious.

In response, Applicant asserts that Anderson et al. does not disclose the invention substantially as claimed, and therefore the rejection fails. Claims 46 and 47 depend upon claim 40 and for the above discussed reasons offered in response to the rejection to claim 40, Anderson et al. does not disclose the invention substantially as claimed, and as such the asserted rejection fails and Applicant respectfully requests that the rejections be withdrawn.

Conclusion

For the above reasons, the claims are believed to be in condition for allowance. Reconsideration is respectfully requested. Applicant requests that the Examiner call if further changes or discussions are believed by the Examiner to be necessary to place the case in condition for allowance prior to further action.

Respectfully submitted,

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